DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
FAX: 504-253-4520

January 13, 2005

WARNING LETTER NO. 2005-NOL-10

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Steven H. Loga, President
Warehouse Food Group, L.L.C.
9122 Grand Caillou Road
Dulac, Louisiana 70353

Dear Mr. Loga:

On November 18, 19 and 29, 2004, a United States Food and Drug Administration (FDA) investigator inspected your seafood processing facility, located at 9122 Grand Caillou Road, Dulac, Louisiana. We found you have serious deviations from the Seafood Hazard Analysis Critical Control Points (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly, your histamine forming fishery products are adulterated, as the amberjack, mahi-mahi, escolar, mackerel, tuna, and wahoo have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's Internet home page at http://www.fda.gov.

The deviations are as follows:

- Pursuant to 21 CFR 123.6(a), your firm must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards reasonably likely to occur for each fish or fishery product you process and to identify the preventive measures that you can apply to control those hazards. In addition, pursuant to 21 CFR 123.6(b), you must have and implement a written HACCP plan to control any food safety hazards reasonably likely to occur. A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm does not have a HACCP plan for amberjack, mahi-mahi, escolar, mackerel, tuna, or wahoo to control the food safety hazard of *Scombrotoxin* (histamine) formation. In fact, your firm has not conducted a hazard analysis for these fish or fishery products.

- Pursuant to 21 CFR 123.9(b)(1), your firm must retain records at the processing facility for at least one (1) year after the date they were prepared in the case of refrigerated products. However, your firm failed to retain receiving records for its histamine fish for at least one year.

We previously sent you Warning Letter No. 2004-NOL-30, dated July 27, 2004, for your Warehouse Food Group, L.L.C. seafood processing facility in Baton Rouge, Louisiana. The letter called to your attention deficiencies the same as or similar to those listed in this letter, such as the failure to have a HACCP plan and the failure to have adequate records. We are concerned you have not responded to the July 2004 warning letter and have not corrected the deficiencies cited in that letter. We may take further action if you do not correct the violations set forth in this letter promptly. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

We recognize at the close of the inspection you made a verbal commitment to correct the observed deficiencies. However, we request you notify this office in writing within 15 working days from your receipt of this letter, of the specific steps you have taken to correct these deviations. You should include in your response documentation, such as a HACCP plan for your histamine forming fishery products, fish receiving records or other useful information to assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring your processing plant operates in compliance with the Act, Seafood HACCP regulations, and Current Good Manufacturing Practice regulations, 21 CFR 110. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Ms. Nicole F. Hardin, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Hardin at (504) 253-4519.

Sincerely,

H. Tyler Thornburg
District Director
New Orleans District

Enclosures: Form FDA 483
21 CFR 110, 21 CFR 123